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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,404

04/22/2005

William Merrill

1054-003

9131

34060

7590

08/19/2008

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EXAMINER

MAUST, TIMOTHY LEWIS

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,404	<b>Applicant(s)</b> MERRILL ET AL.	
	<b>Examiner</b> Timothy L. Maust	<b>Art Unit</b> 3751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 33-76 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/07 and 7/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Claims 1-32 in the reply filed on 5/12/08 is acknowledged. The traversal is on the ground(s) that lack of unity has not been shown. This is not found persuasive because the method, as claimed, doesn't define the technical feature of a manually removable filling needle coupled via a disposable tubing to a pumping device. The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claims 31 and 32, it is unclear as to how no components or no moving components are located downstream when the majority of the components are located downstream.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-22, 24-26 and 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Odell et al. (6,263,641)

In regard to claim 1, a method comprising a plurality of activities comprising: via a system (see Figure 10) comprising an autoclaveable automatic non-electrically-driven container positioner (84 and 92), automatically transporting a container (i.e., syringe) within a critical zone (222) located in an airflow that encounters no Class 100 contaminant generators upstream from the critical zone, the container positioner located downstream from a filling inlet of the container; and automatically introducing a filling to the container via the filling inlet of the container (see Figure 10; 232).

In regard to claim 2, further comprising: preloading the container into the system (Figure 10 ; 220).

In regard to claims 3 and 24. The method of claim i, further comprising: providing the container to the container positioner (column 10, line 63 – column 11, line 11; i.e., robotic or human transfer). If machine transferred, human contact would be absent.

In regard to claim 4, further comprising: preloading a closure into the system (174).

In regard to claims 5, 20-22, 25 and 30, further comprising: shielding the container from contamination (see single housing 108).

In regard to claim 6, further comprising: shielding the container from contamination when outside the critical zone (see single housing 108).

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In regard to claim 7, further comprising: shielding a closure from contamination (see single housing 108).

In regard to claim 8, further comprising: shielding a closure from contamination when outside the critical zone (see single housing 108).

In regard to claim 9, further comprising: providing a closure to the container (i.e., stopper supply 234).

In regard to claims 10 and 13, further comprising: positioning a closure on the container (242).

In regard to claim 11, further comprising: positioning a closure on the container while the container is within the critical zone (see Figure 10).

In regard to claim 12, further comprising: automatically positioning a closure on the container (see col. 12, line 65 to col. 13, line 6).

In regard to claims 14-19, cover sheet 102 is sealed or crimped over the syringes after being placed in the tray 84 and tub 92.

In regard to claim 26, the weight of the container positioner (84 and 92) is inherently less than 60 pounds.

In regard to claims 28 and 29, the system is capable of being manually assembled with or without tools.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Odell et al.

In regard to claim 23, the Odell et al. reference discloses the invention substantially as claimed, but doesn't disclose the container positioner being driven pneumatically. It would have been obvious to one having ordinary skill in the art at the time the invention was made to drive the container positioner, "mechanically", "electromagnetically", "pneumatically" or "hydraulically", since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

In regard to claim 27, the Odell et al. reference discloses the invention substantially as claimed, but doesn't disclose the weight of the system weighing less than 300 pounds. It would have been obvious to one having ordinary skill in the art at the time the invention was made to design a system that weighs less than 300 pounds, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy L. Maust whose telephone number is (571) 272-4891. The examiner can normally be reached on Mon. - Thur. 7:00-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Greg Huson can be reached on (571) 272-4883. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy L Maust/  
Primary Examiner  
Art Unit 3751

Tlm  
8/11/08